

08/807,506



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EXAMINER

BUDENS, R

ART UNIT PAPER NUMBER

1648

14

DATE MAILED: 09/14/99

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

## OFFICE ACTION SUMMARY

- ☒ Responsive to communication(s) filed on 6/23/99
- ☒ This action is FINAL

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

- ☒ Claim(s) 94-132 is/are pending in the application.
- Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 94-125, 127, 130-132 is/are rejected.
- ☒ Claim(s) 126, 128, 129 is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☒ All ☒ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received:
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- ☐ Notice of Reference Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

-SEE OFFICE ACTION ON THE FOLLOWING PAGES-

BEST AVAILABLE COPY

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The status of the related application(s) cited at the first page of the specification should be updated, if necessary, to ensure a properly completed file record.

5 The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

10 The Examiner acknowledges Applicant's Amendment, Paper No. 13, filed June 23, 1999. In view of Applicant's Amendment, the status of the claims is as follows: Claims 1-93 have been canceled; Claims 94-132, newly added, are currently pending before the Examiner.

15 Claim 126, 128 and 129 are objected to under 37 C.F.R. 1.75(c) as being in improper form because a multiple dependent claim should only refer to other claims in the alternative and cannot depend from other multiple dependent claims. See M.P.E.P. 608.01(n). Accordingly, claims 126, 128 and 129 are not been further treated on the merits.

20 Applicant is again reminded that the specification must be amended in accordance with the form PTO 948 attached to the last Office Action. **While submission of formal drawings can be held in abeyance until such time as allowable subject matter is determined, Applicant is required to amend the Brief Description of the Drawings, if necessary, in response to this Office Action to properly reflect the required corrections of the Drawings.** Applicant is reminded that the instant application does not even  
25 contain a proper Brief Description of the Drawings and Applicant has failed to properly amend the specification to correct these deficiencies.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

**The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.**

Claims 94-132 are rejected under 35 U.S.C. § 112, second  
5 paragraph, as being indefinite for failing to particularly point  
out and distinctly claim the subject matter which applicant regards  
as the invention. Claims 94 and 122 are vague and indefinite in  
the recitation "is introduced" since it is entirely unclear what  
"is introduced" into said proteins. Amendment of claims 94 and 122  
10 to more clearly define the invention would obviate this rejection.  
Claim 100 is vague and indefinite in the recitation "LDMS" since  
the abbreviation is not disclosed in the claims. Amendment of  
claim 100 to recite the full description of "LDMS" would obviate  
this rejection. Claims 104, 109, 111, 113, 115, 125 and 127-128  
15 are vague and indefinite in the recitation "and/or" since it is  
entirely unclear what is encompassed by the claimed invention.  
Amendment of the claims to recite "and" or "or" would obviate this  
rejection. Claims 104, 108, 109, 121 and 130 are vague and  
indefinite in the recitation "e.g.," or "for example," or "for  
20 instance," or such similar language since it is unclear whether the  
limitations following the phrase are part of the claimed invention.  
Amendment of the claims to delete "e.g.," or similar language would  
obviate this rejection. Claim 104 is vague and indefinite in the  
recitation "gradually varying conditions" since it is entirely  
25 unclear to what extent and at what rate conditions are varied.  
Amendment of claim 104 to more clearly define the invention would  
obviate this rejection. Claims 107 and 112-114 are vague and  
indefinite in the recitation "close proximity" since it is unclear  
what distance would be encompassed by "close proximity." Amendment  
30 of the claims to more clearly define the invention would obviate  
this rejection. Claim 112 is vague and indefinite in the  
recitation "and a colony stimulating factor" since claim 112 is an  
improper Markush grouping. Amendment of claim 112 to correctly set  
forth the members of the Markush grouping would obviate this

rejection. Claim 113 is vague and indefinite in the recitation "same (cytokine) superfamily" since it is unclear what superfamily Applicant is actually claiming. Amendment of claim 113 to more clearly define the claimed invention would obviate this rejection.

5 Claim 119 is vague and indefinite in the recitation "almost 50%" since it is unclear what range of inhibition is actually being claimed. Amendment of claim 119 to delete "almost" would obviate this rejection. Claim 123 is vague and indefinite in the recitation "significant inhibition" since it is unclear what amount

10 of inhibition would constitute "significant inhibition." Amendment of claim 123 to more clearly define the invention would obviate this rejection. Claim 128 is vague and indefinite in the recitation "apoptose" since it is unclear what is meant by "apoptose." Amendment of claim 128 to recite "apoptosis-inducing"

15 would obviate this rejection. Claim 132 is vague and indefinite in the recitation "any of the method steps of claim 94" since it is entirely unclear what steps or groups of steps would result in the substance suitable for the method of claim 132. Amendment of claim 132 to delete "any of the steps" would obviate this rejection.

20 The following is a quotation of the first paragraph of 35 U.S.C. § 112:

25 The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

30 Claims 125 and 127 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for the reasons of record set forth

in the last Office Action. Applicant's arguments have been fully considered but are not deemed persuasive to overcome the rejection. Claims 125 and 127 appear to replace claim 78. The claimed invention is directed to methods of treating HIV by lowering antibody levels. As stated previously, Applicant has not established that lowering antibody levels by any of the claimed means would necessarily result in inhibition, suppression or cure of HIV. Indeed, one skilled in the art would reasonably conclude that lowering antibody levels in a host would favor the HIV infection rather than suppressing or inhibiting the infection. Nor does the specification establish that lowering any antibody level would result in inhibition of HIV infection. In the absence of convincing objective evidence, the rejection is maintained.

Claims 94-132 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claimed invention is directed to methods and substances modified in any number of ways to produce any number of effects and alleged to be suitable in therapeutic methods of stimulating stem cell replication, treating and/or preventing HIV infection, or for gene therapy. However, it is well known by those skilled in the art that modification of peptides and proteins is a highly unpredictable process relying predominantly on trial and error. Applicant has encompassed considerable breadth in the scope of the claimed invention but has not provided sufficient teachings or working examples to allow one skilled in the art to make and use the claimed invention with a reasonable expectation of success and without undue experimentation. Modification of even a single amino acid of a protein can have dramatic and often disastrous results. In the case of antibodies and antigens, modification of a single amino acid of an antibody or an antigen can result in decreasing or abrogating antigen-antibody

interactions. In the case of hemoglobin, a single amino acid change results in sickle cell disease. Here Applicant has essentially claimed any modification or group of modifications but has not set forth sufficient teachings to give one skilled in the art a reasonable expectation of success in making and using the claimed invention without undue experimentation. Applicant's claimed invention essentially constitutes an invitation to experiment. This is not sufficient to meet the requirement of 35 U.S.C. § 112, first paragraph.

It is respectfully suggested that Applicant consider scheduling an interview with the Examiner to provide Applicant an opportunity to discuss and describe the claimed invention to help the Examiner and the Applicant understand each other's position. The Examiner's opinion is that such an interview may be helpful to both the Examiner in understanding Applicant's invention and to the Applicant in understanding the Examiner's position with respect to the claimed invention. The presently claimed invention is sufficiently vague and indefinite and of such breadth as to render it impossible for the Examiner to adequately search the prior art and to determine the relevancy of the prior art to the claimed invention. For this reason, the Examiner respectfully suggests that Applicant schedule an interview with the Examiner for the purpose of furthering the prosecution of this application.

No claim is allowed.

Applicant's amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

**A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING**

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5 DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED  
UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD,  
THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE  
ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37  
C.F.R. 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE  
ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR  
RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL  
ACTION.

10 Papers relating to this application may be submitted to Group  
1600 by facsimile transmission. The Fax number is (703) 308-4242.  
Please note that the faxing of such papers must conform with the  
Notice published in the Official Gazette, 1096 OG 30, (November 15,  
1989).

15 Any inquiry concerning this communication or earlier  
communications from the Examiner should be directed to Robert D.  
Budens at (703) 308-2960. The Examiner can normally be reached  
Monday-Thursday from 6:30 AM-4:00 PM, (EST). The Examiner can also  
be reached on alternate Fridays. If attempts to reach the Examiner  
by telephone are unsuccessful, the Examiner's supervisor, Chris  
20 Eisenschenk, can be reached at (703) 308-0452.

Any inquiry of a general nature or relating to the status of  
this application should be directed to the Group receptionist at  
(703) 308-0196.



Robert D. Budens  
Primary Examiner  
Art Unit 1648

rdh  
September 12, 1999